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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,422	10/22/2007	John L. Telford	002441.00189	9353

27476 7590 11/29/2010

NOVARTIS VACCINES AND DIAGNOSTICS INC.
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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,422	TELFORD ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,14,16-20,28 and 29* is/are pending in the application.

4a) Of the above claim(s) *5-7,14 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,9,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendments

1) Acknowledgment is made of Applicants' amendment filed 09/20/10 and 01/15/2010 in response to the non-final Office Actions mailed 06/23/10 and 11/10/09.

Status of Claims

2) Claims 1, 3-12, 14, 16, 17, 19, 20, 22-26, 28 and 29 have been amended via the amendment filed 04/05/10.

Claims 2, 13, 15, 21, 27 and 30 have been canceled via the amendment filed 04/05/10.

Claims 10-12 and 22-26 have been canceled via the amendment filed 08/06/10.

Claim 20 has been amended via the amendment filed 09/20/10.

Claims 1, 3-9, 14, 16-20, 28 and 29 are pending.

The at least one different GBS antigen in the amended claim 14 is currently drawn to a non-elected species. Therefore, claim 14 and the claims dependent therefrom are withdrawn from consideration as being directed to non-elected species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1, 3, 4, 8, 9, 28 and 29 are under examination.

Substitute Sequence Listing

3) Acknowledgment is made of Applicants' submission of the substitute sequence listing and CRF which have been entered on 01/29/2010.

Objection(s) Moot

4) The objection to claims 15, 27 and 30 made in paragraph 14 of the Office Action mailed 11/10/09 is moot in light of Applicants' cancellation of the claims.

Objection(s) Withdrawn

5) The objection to the specification made in paragraph 7 of the Office Action mailed 11/10/09 is withdrawn in light of Applicants' amendment to the specification.

6) The objection to claims 1, 8, 10, 14, 16, 17, 28 and 29 made in paragraph 14 of the Office Action mailed 11/10/09 is withdrawn. Applicants state that a space is not required after the limitation 'NO:'.

Rejection(s) Moot

7) The rejection of claim 27 made in paragraph 9 of the Office Action mailed 11/10/09 under 35 U.S.C. § 101 as being directed to non-statutory subject matter is moot in light of Applicants' cancellation of the claim.

8) The rejection of claims 2, 10, 15, 27 and 30 made in paragraph 11 of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 2, 10, 15, 27 and 30 made in paragraph 13 of the Office Action mailed 11/10/09 under 35 U.S.C. § 102(e)(1) as being anticipated by Tettelin *et al.* (WO 2004/018646 A2 – Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

10) The rejection of claims 1 and 14 made in paragraph 9 of the Office Action mailed 11/10/09 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claims.

11) The rejection of claims 1, 3, 4, 8, 9, 14, 16 and 17 made in paragraph 11(a) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as

being indefinite, is withdrawn in light of Applicants' amendment to the claims or the base claim.

12) The rejection of claims 1, 14, 16 and 17 made in paragraph 11(b) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

13) The rejection of claim 1 made in paragraph 11(d) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 14 made in paragraph 11(e) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claim 8 made in paragraph 11(i) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 16 made in paragraph 11(k) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 17 made in paragraph 11(l) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 28 made in paragraph 11(m) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 29 made in paragraph 11(n) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claims 3, 4, 8, 9, 16, 17 and 29 made in paragraph 11(o) of the Office Action mailed 11/10/09 under 35 U.S.C. § 112, second paragraph as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

21) The rejection of claims 14-17 made in paragraph 13 of the Office Action mailed 11/10/09 under 35 U.S.C. § 102(e)(1) as being anticipated by Tettelin *et al.* (WO 2004/018646 A2, of record), is withdrawn in light of Applicants' amendment to claim 14. Applicants' arguments with regard to these claims are moot.

Rejection(s) Maintained

22) The rejection of claims 1, 3, 4, 8, 9, 28 and 29 made in paragraph 13 of the Office Action mailed 11/10/09 under 35 U.S.C. § 102(e)(1) as being anticipated by Tettelin *et al.* (WO 2004/018646 A2, of record), is maintained for the reasons set forth therein and herein below.

Applicants cite case law and contend that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicants opine that Tettelin does not meet this standard. Applicants state that the independent claim 1 is directed to a composition comprising two isolated GBS antigens: (1) a GBS 80 antigen or a fragment thereof, wherein the GBS 80 antigen comprises an amino acid sequence selected from the group consisting of SEQ ID NOS: 2, 3, 4, 6, 7, 8, and 9; and (2) a GBS 322 antigen or a fragment thereof, wherein the GBS 322 antigen comprises the amino acid sequence SEQ ID NO: 38. Applicants conclude that Tettelin does not disclose this composition and does not anticipate claim 1 or its dependent claims.

Applicants' arguments have been carefully considered, but are not persuasive.

First, the instant claims include the open claim language 'comprising'. The transitional limitation 'comprising' represents open-ended claim language and therefore, does not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). Therefore, the limitation 'comprising' in the instant claim(s) allows any number of isolated GBS polypeptides to be present in the claimed composition as long as the recited GBS polypeptides are comprised therein.

Second, the limitation 'at least one GBS polypeptide antigens' in claim 1, for example, places no upper limit to the number of GBS polypeptide antigens that can be present in the claimed composition along with GBS 80 and GBS 322 proteins having SEQ ID NO: 8780 (i.e., the instantly recited SEQ ID NO: 2) and SEQID NO: 8540 (i.e., the instantly recited SEQ ID NO: 322).

As set forth previously, the instant invention is taught by the single prior art reference of Tettelin *et al.* Tettelin *et al.* taught an immunogenic composition comprising two or more GBS polypeptides or fragments thereof, or ***a fusion protein*** thereof. One combination composition consists of two GBS polypeptides or fragments thereof. The composition comprises an adjuvant and induces a protective immune response particularly in a human. See claims 1-9; last paragraph on pages 10 and 21; fourth full paragraph on page 11; pages 13 and 14; third full paragraph on page 22; 'Vaccines and Immunisation' beginning on page 23; pages 29-33 including the first and fifth full paragraphs of page 32; and 'Pharmaceutical Compositions' and 'Vaccines' on pages 63-65 and 70. The amino acid sequences

of the prior art have 100% sequence identity with the instantly recited amino acid sequences of SEQ ID NO: 3, SEQ ID NO: 38 and SEQ ID NO: 7 respectively. See the sequence alignments below.

SEQ ID NO: 3

```
ADL00034
ID   ADL00034 standard; protein; 554 AA.
AC   ADL00034;
DT   15-JUN-2007  (revised)
DT   20-MAY-2004  (first entry)
DE   Streptococcus agalactiae ORF SAG0645-related protein 1.
KW   immunogenic composition; group B Streptococcus; GBS; antibacterial;
KW   streptococcal infection; vaccine; SAG; BOND_PC;
KW   cell wall surface anchor family protein; hypothetical protein;
KW   hypothetical protein gbs0628 [Streptococcus agalactiae NEM316];
KW   Unknown [Streptococcus agalactiae NEM316]; GO9986.
OS   Streptococcus agalactiae 2603V/R.
PN   WO2004018646-A2.
PD   04-MAR-2004.
PF   26-AUG-2003; 2003WO-US026827.
PR   26-AUG-2002; 2002US-0406237P.
PR   27-AUG-2002; 2002US-0406676P.
PR   28-AUG-2002; 2002US-0406757P.
PA   (CHIR ) CHIRON CORP.
PA   (GENO-) INST GENOMIC RES.
PI   Tettelin H,  Masignani V;
DR   WPI; 2004-248071/23.
DR   PC:NCBI; gi22536814.
PT   Immunogenic composition useful as a vaccine for treating or preventing
PT   streptococcal infections, comprises group B Streptococcus polypeptides.
PS   Claim 10; SEQ ID NO 8710; 1194pp; English.
CC   The invention relates to a novel immunogenic composition comprising a
CC   combination of 2-5 group B Streptococcus (GBS) polypeptides. Each
CC   polypeptide is encoded by a GBS polynucleotide sequence which is
CC   homologous to a polynucleotide sequence of group A Streptococcus (GAS),
CC   Streptococcus pneumoniae and/or least one other GBS serotype. The
CC   composition of the invention demonstrates antibacterial activity whilst
CC   the polypeptides and polynucleotides may be useful in assays to diagnose
CC   and identify streptococcal infections or for identifying, screening and
CC   developing vaccines and other treatments for streptococcal infections.
CC   The current sequence is that of a Streptococcus agalactiae ORF SAG
CC   protein of the invention.
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
SQ   Sequence 554 AA;

  Query Match           100.0%;  Score 2642;  DB 1;  Length 554;
  Best Local Similarity   100.0%;
  Matches  517;  Conservative  0;  Mismatches  0;  Indels  0;  Gaps  0.

Qy          1 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         38 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 97
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Qy          61 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 120
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          98 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 157

Qy         121 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 180
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         158 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 217

Qy         181 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 240
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         218 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 277

Qy         241 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 300
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         278 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 337

Qy         301 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 360
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         338 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 397

Qy         361 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 420
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         398 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 457

Qy         421 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 480
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         458 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 517

Qy         481 RPSIPNTGGIGTAIFVAIGAAVMAFAVKGMKRRTKDN 517
               |||||||||||||||||||||||||||||||||||||
Db         518 RPSIPNTGGIGTAIFVAIGAAVMAFAVKGMKRRTKDN 554
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SEQ ID NO: 38

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ADK99683
ID   ADK99683 standard; protein; 417 AA.
AC   ADK99683;
DT   20-MAY-2004  (first entry)
DE   Streptococcus agalactiae ORF SAG0032-related protein 11.
KW   immunogenic composition; group B Streptococcus; GBS; antibacterial;
KW   streptococcal infection; vaccine; SAG.
OS   Streptococcus agalactiae.
PN   WO2004018646-A2.
PD   04-MAR-2004.
PF   26-AUG-2003; 2003WO-US026827.
PR   26-AUG-2002; 2002US-0406237P.
PR   27-AUG-2002; 2002US-0406676P.
PR   28-AUG-2002; 2002US-0406757P.
PA   (CHIR ) CHIRON CORP.
PA   (GENO-) INST GENOMIC RES.
PI   Tettelin H,  Masignani V;
DR   WPI; 2004-248071/23.
PT   Immunogenic composition useful as a vaccine for treating or preventing
PT   streptococcal infections, comprises group B Streptococcus polypeptides.
PS   Claim 10; SEQ ID NO 6922; 1194pp; English.
CC   The invention relates to a novel immunogenic composition comprising a
CC   combination of 2-5 group B Streptococcus (GBS) polypeptides. Each
CC   polypeptide is encoded by a GBS polynucleotide sequence which is
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CC   homologous to a polynucleotide sequence of group A Streptococcus (GAS),
CC   Streptococcus pneumoniae and/or least one other GBS serotype. The
CC   composition of the invention demonstrates antibacterial activity whilst
CC   the polypeptides and polynucleotides may be useful in assays to diagnose
CC   and identify streptococcal infections or for identifying, screening and
CC   developing vaccines and other treatments for streptococcal infections.
CC   The current sequence is that of a Streptococcus agalactiae ORF SAG
CC   protein of the invention.
SQ   Sequence 417 AA;

  Query Match             100.0%;  Score 1968;  DB 1;  Length 417;
  Best Local Similarity   100.0%;
  Matches  392;  Conservative  0; Mismatches  0; Indels 0; Gaps 0.

Qy          1 DLVKQDNKSSYTVKYGDTLSVISEAMSIDMNVLAKINNIADINLIYPETTLTVTYDQKSH 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 DLVKQDNKSSYTVKYGDTLSVISEAMSIDMNVLAKINNIADINLIYPETTLTVTYDQKSH 60

Qy         61 TATSMKIETPATNAAGQTTATVDLKTNQVSVADQKVSLNTISEGMTPEAATTIVSPMKTY 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 TATSMKIETPATNAAGQTTATVDLKTNQVSVADQKVSLNTISEGMTPEAATTIVSPMKTY 120

Qy        121 SSAPALKSKEVLAQEQAVSQAAANEQVSPAPVKSITSEVPAAKEEVKPTQTSVSQSTTVS 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SSAPALKSKEVLAQEQAVSQAAANEQVSPAPVKSITSEVPAAKEEVKPTQTSVSQSTTVS 180

Qy        181 PASVAAETPAPVAKVAPVRTVAAPRVASVKVVTPKVETGASPEHVSAPAVPVTTTSPATD 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 PASVAAETPAPVAKVAPVRTVAAPRVASVKVVTPKVETGASPEHVSAPAVPVTTTSPATD 240

Qy        241 SKLQATEVKSVPVAQKAPTATPVAQPASTTNAVAAHPENAGLQPHVAAYKEKVASTYGVN 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 SKLQATEVKSVPVAQKAPTATPVAQPASTTNAVAAHPENAGLQPHVAAYKEKVASTYGVN 300

Qy        301 EFSTYRAGDPGDHGKGLAVDFIVGTNQALGNKVAQYSTQNMAANNISYVIWQQKFYSNTN 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 EFSTYRAGDPGDHGKGLAVDFIVGTNQALGNKVAQYSTQNMAANNISYVIWQQKFYSNTN 360

Qy        361 SIYGPANTWNAMPDRGGVTANHYDHVHVSFNK 392
              ||||||||||||||||||||||||||||||||
Db        361 SIYGPANTWNAMPDRGGVTANHYDHVHVSFNK 392
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SEQ ID NO: 7

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ADL00034
ID   ADL00034 standard; protein; 554 AA.
AC   ADL00034;
DT   15-JUN-2007  (revised)
DT   20-MAY-2004  (first entry)
DE   Streptococcus agalactiae ORF SAG0645-related protein 1.
KW   immunogenic composition; group B Streptococcus; GBS; antibacterial;
KW   streptococcal infection; vaccine; SAG; BOND_PC;
KW   cell wall surface anchor family protein; hypothetical protein;
KW   hypothetical protein gbs0628 [Streptococcus agalactiae NEM316]; Unknown;
KW   Unknown [Streptococcus agalactiae NEM316]; GO9986.
OS   Streptococcus agalactiae 2603V/R.
PN   WO2004018646-A2.
PD   04-MAR-2004.
PF   26-AUG-2003; 2003WO-US026827.
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PR 26-AUG-2002; 2002US-0406237P.
PR 27-AUG-2002; 2002US-0406676P.
PR 28-AUG-2002; 2002US-0406757P.
PA (CHIR) CHIRON CORP.
PA (GENO-) INST GENOMIC RES.
PI Tettelin H, Masignani V;
DR WPI; 2004-248071/23.
DR PC:NCBI; gi22536814.
PT Immunogenic composition useful as a vaccine for treating or preventing
PT streptococcal infections, comprises group B Streptococcus polypeptides.
PS Claim 10; SEQ ID NO 8710; 1194pp; English.
CC The invention relates to a novel immunogenic composition comprising a
CC combination of 2-5 group B Streptococcus (GBS) polypeptides. Each
CC polypeptide is encoded by a GBS polynucleotide sequence which is
CC homologous to a polynucleotide sequence of group A Streptococcus (GAS),
CC Streptococcus pneumoniae and/or least one other GBS serotype. The
CC composition of the invention demonstrates antibacterial activity whilst
CC the polypeptides and polynucleotides may be useful in assays to diagnose
CC and identify streptococcal infections or for identifying, screening and
CC developing vaccines and other treatments for streptococcal infections.
CC The current sequence is that of a Streptococcus agalactiae ORF SAG
CC protein of the invention.
CC Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC information from BOND.
SQ Sequence 554 AA;

Query Match 100.0%; Score 2473; DB 1; Length 554;
Best Local Similarity 100.0%;
Matches 483; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

```
Qy          1 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         38 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 97

Qy         61 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         98 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 157

Qy        121 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        158 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 217

Qy        181 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        218 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 277

Qy        241 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        278 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 337

Qy        301 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        338 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 397

Qy        361 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        398 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 457

Qy        421 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 480
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                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        458 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 517

Qy        481 RPS 483
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Db        518 RPS 520
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Since the prior art GBS polypeptides or fragments are identical in structure or amino acid composition with the instantly recited polypeptides or fragments, they are expected to necessarily possess the same identical function(s) recited in the instant claims, i.e., improved immunogenicity as measured by the Active Maternal Immunization Assay and higher percent survival rate in challenged pups from female mice immunized with a single non-GBS 80 antigen. The functions recited by Applicants are viewed as inherent properties inseparable from the prior art products. Products identical in structure cannot have mutually exclusive properties.

Claims 1, 3, 4, 8, 9, 28 and 29 are anticipated by Tettelin *et al.* The rejection stands.

New Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C. § 112, First Paragraph

23) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24) Claim 1, as amended, and the dependent claims 3, 4, 8 and 9 are rejected are rejected under 35 U.S.C. § 112, first paragraph, as being under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended, includes the new limitations: or a fragment 'of the GBS 80 antigen, wherein the GBS 80 antigen comprises an amino acid sequence selected from the group consisting of SEQ ID NOS: 2, 3, 4, 6, 7, 8, and 9 and wherein the fragment of the GBS antigen comprises an immunogenic epitope; and the second isolated GBS antigen is a GBS 322 antigen or a fragment of the GBS 322 antigen, wherein the GBS 322 antigen comprises the amino acid sequence SEQ ID NO:38 and wherein the fragment of the GBS 322 antigen comprises an immunogenic wherein, in an Active Maternal Immunization Assay, GBS-challenged pups from female mice immunized with the combination have an improved survival rate compared with GBS-challenged pups from female mice immunized with a single antigen, wherein the single antigen is not GBS 80'. Applicants state that the specification supports this amendment, for example, on page 3, lines 11-18 and on page 5, lines 13-18. Applicants submit that particular fragments of GBS 80 are disclosed on pages 5-7 and in Tables 1 and 2 on page 8 and that particular fragments of GBS 322 are disclosed on pages 28-29. However, these parts of the specification including the contents of Tables 1 and 2 do not provide descriptive support for a composition comprising the bivalent combination species of GBS 80, SEQ ID NO: 7 and GBS 322 species, SEQ ID NO: 38, or immunogenic epitope-containing fragments thereof 'wherein, in an Active Maternal Immunization Assay, GBS-challenged pups from female mice immunized with the combination have an improved survival rate compared with GBS-challenged pups from female mice immunized with a single antigen, wherein the single antigen is not GBS 80'. Table 2 is unrelated to 'Active Maternal Immunization Assay'. Table 1 does not show active maternal immunization results using a combination of GBS 80, SEQ ID NO: 7 and GBS 322 species, SEQ ID NO: 38, or immunogenic epitope-containing fragments thereof, wherein, in the

Active Maternal Immunization Assay, GBS-challenged pups from female mice immunized with *the combination* have an improved survival rate compared with GBS-challenged pups from female mice "*immunized with a single antigen, wherein the single antigen is not GBS 80*". The negative limitation 'a single antigen .... that is not GBS 80' is of enormous scope encompassing a single antigen of any eukaryote, prokaryote, bacteria, non-bacteria, parasite, fungus, GBS, non-GBS etc., for which there is no written description support in the identified parts of the as-filed specification. Therefore, the above-identified limitation(s) in the claim(s) are considered to be new matter. See M.P.E.P 608.04 to 608.04(c).

Applicant is invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitation(s) identified above, or alternatively, remove the new matter from the claim(s). Applicant should specifically point out the support for any amendment made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

25) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

26) Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

Claim 3, as amended, is indefinite because it lacks proper antecedence in the limitations 'GBS-challenged pups'. See lines 2-4. Claim 2 depends from claim 1, which already includes the limitation 'GBS-challenged pups' therein. For proper

antecedent basis, it is suggested that Applicants replace each of the above-identified limitations with the limitation --the GBS-challenged pups--.

Remarks

27) Claims 1, 3, 4, 8, 9, 27 and 29 stand rejected.

In line 10 of claim 1, for clarity and consistency with the claim language used in claim 8, it is suggested that Applicants replace the limitation 'the amino acid sequence SEQ ID' with the limitation --the amino acid sequence of SEQ ID--.

In line 2 of claim 9, for clarity and consistency with the claim language used in claim 8, it is suggested that Applicants replace the limitation 'the amino acid sequence SEQ ID' with the limitation --the amino acid sequence of SEQ ID--.

28) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

30) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

31) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting Supervisor, Patricia Duffy, can be reached on (571) 272-0855.

/S. Devi/
Primary Examiner
AU 1645

November, 2010